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K032613

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510(k) SUMMARY OF DEVICE

TRADE NAME: PACER ASSIST DEVICE (FORMAL NAME TO BE COPYRIGHTED ON RECEIPT OF 510(K) CLEARANCE)

COMMON NAME: ACCESSORY TO EKG CABLE

CLASSIFICATION NAME: ACCESSORY TO EKG CABLE (CLASSIFICATION TO BE DETERMINED)

CONTACT PERSON: PETER M. ROTHENBERG, M.D., M.A.

As noted in my 510 (k) application, this device is of such simplicity, there are no others *directly* comparable. Features have been incorporated into those far more technologically advanced. In essence, the subject device provides an electrically safe connection between the proximal pin of an intravascular electrode and a patient EKG lead , the signal ultimately traveling retrograde along a standard EKG cable to a bedside monitor. It would be used to facilitate placement of a transvenous pacemaker or appropriately designed intravenous catheter with *EKG* guidance rather than the more cumbersome (and expensive) fluoroscopic approach.

The device entirely consists of a pin jack (to accept the proximal pin of the electrode) connected in series via a 1000 ohm resistor to a standard EKG eyelet all encased in an appropriate housing. The snap-fit connection between the EKG lead and device eyelet completes the connection to the monitor.

DATE PREPARED: 10/27/03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Peter M. Rothenberg, M.D., M.A.
657 Camino De Los Mares
Suite 137
San Clemente, CA 92673

Re: K032613
Trade Name: Transvenous Pacemaker Placement Assist Device
Regulation Number: 21 CFR 870.3680 and 870.2050
Regulation Name: Accessory to cardiovascular permanent or temporary pacemaker electrode; and biopotential amplifier and signal conditioner
Regulatory Class: Class II (two)
Product Code: LDF and DRR
Dated: October 30, 2003
Received: November 4, 2003

Dear Dr. Rothenberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

This device is designed to connect an intravascular electrode to a monitor through a standard EKG patient lead for the purpose of displaying an intravascular signal in real time. Only the black pinjack is "active". The red pinjack is electrically blind and designed to isolate the proximal electrode from inadvertent stimulation.

X - prescription device

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032613